IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691-GBW **UNSEALED ON 9/15/2025**
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1138-GBW **UNSEALED ON 9/15/2025**
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-1594-GBW **UNSEALED ON 9/15/2025**

MEMORANDUM ORDER

Pending before the Court is Plaintiffs' Renewed Motion for a Permanent Injunction (D.I. 746) ("Plaintiffs' Motion"), which has been fully briefed (D.I. 747; D.I. 757; D.I. 768).[1] For the following reasons, Plaintiffs' Motion is denied.[2]

I. BACKGROUND

A. The Federal Circuit's *Jazz II* Opinion

Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Jazz") obtained injunctive relief from this Court, *see* D.I. 665, after the parties stipulated "that Avadel's manufacture, use, offers for sale, sales, and/or importation of Avadel's Lumryz™ drug product infringes claim 24 of the [11,147,782] patent [(''782 patent')] pursuant to 35 U.S.C. § 271(a), to the extent claim 24 of the '782 patent is found not to be invalid or unenforceable." D.I. 550 at 2.

"Avadel CNS Pharmaceuticals, LLC ('Avadel') appeal[ed] [] the decision . . . permanently enjoining it from seeking approval from the U.S. Food and Drug Administration ('the FDA') of its product, Lumryz, for the treatment of idiopathic hypersomnia [('IH')], as well as from marketing Lumryz for that indication." *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 136 F.4th 1075, 1077 (Fed. Cir. 2025) ("*Jazz II*"). As explained below, on May 6, 2025, the Federal Circuit addressed "whether th[is] district court abused its discretion by enjoining Avadel from applying

[1] Unless otherwise noted, references to docket cites refer to C.A. No. 21-691-GBW.

[2] The Court "determines that the facts and legal arguments in the briefs and record are adequate, and the decisional process would not be significantly aided by oral argument." *In re Trib. Media Co.*, 587 B.R. 606, 610 n.3 (D. Del. 2018), *aff'd*, 972 F.3d 228 (3d Cir. 2020). Thus, Plaintiffs' "motion for permanent injunction having been fully briefed, the Court will now consider it on the basis of the parties' submissions without oral argument." *Willow Run Foods, Inc. v. Supply Mgmt. Servs., Inc.*, No. 3:22-CV-170, 2022 WL 1813984, at *1 (N.D.N.Y. June 2, 2022); *see* D. Del. LR 7.1.4 ("An application for oral argument may be granted or denied, in the discretion of the Court.").

for FDA approval of Lumryz for any indication that was not part of its label as of March 4, 2024." *Id.* at 1085.

First, the Federal Circuit "agree[d] [with Defendant] that the submission of an application to the FDA is not infringement under § 271(a)." *Id.* at 1086; *see id.* ("That activity is not a making, using, offering to sell, selling, or importing of a patented invention.").

Second, the Federal Circuit concluded that "[i]f Avadel's submission of its paper [New Drug Application ('NDA')] for Lumryz—for the treatment of IH or any other indication—is an act of infringement under § 271(e)(2), then the district court's injunction barring Avadel from seeking FDA approval of any new indications of Lumryz was unlawful." *Id.* at 1088.

Third, the Federal Circuit concluded that "[i]f, however, Avadel's submission of its paper NDA is *not* an act of infringement under § 271(e)(2), then the remedies available to Jazz are no longer limited by § 271(e)(4)." *Id.* "In that case, ... because that activity would not constitute infringement—under either § 271(e)(2) or § 271(a)—to properly enjoin that activity, the district court must have concluded that the injunction was *necessary* to prevent infringement." *Id.*

The Federal Circuit observed that "[a]lthough Avadel's ability to enter the market is, in part, dependent on Avadel seeking FDA approval, it does not follow that enjoining Avadel's application would be *necessary* to prevent infringement." *Id.* at 1089; *see id.* ("Future infringement, *e.g.*, commercialization of Lumryz for IH, can only occur if and when the FDA approves Lumryz for that indication. And any number of things may prevent that approval from ever arriving. Avadel may decide the financial investment in pursuing the approval does not comport with its business prospects. Clinical trials may fail.").

The Federal Circuit "vacate[d] the injunction to the extent it enjoin[ed] Avadel from seeking FDA approval for new indications of Lumryz, and remand[ed] to th[is] district court for reconsideration of that issue in light of [the Federal Circuit's] opinion." *Id.* at 1089.

B. The May 2025 Joint Status Report

On May 23, 2025, the parties "submit[ted] [a] Post-Appeal Status Report and proposed briefing schedule on how the case should proceed." D.I. 733 at 1. According to the joint status report, "on remand, the parties must address whether Avadel should and/or can be enjoined from seeking FDA approval for an idiopathic hypersomnia ('IH') indication for LUMRYZ™ prior to the expiration of the '782 patent in light of the Federal Circuit's decision." *Id.*

C. Plaintiffs' Motion

"Pursuant to 35 U.S.C. § 283, Plaintiffs . . . move for entry of a renewed permanent injunction against infringement by Defendant . . . of Claim 24 of U.S. Patent No. 11,147,782 (the ''782 patent') by marketing, making, using, or selling Avadel's Lumryz drug product or any product not more than colorably different from Lumryz for the treatment of idiopathic hypersomnia ('IH'), and prohibiting Avadel from seeking approval from the U.S. Food and Drug Administration ('FDA') for IH[.]" D.I. 746 at 1-2.

Under Plaintiffs' proposed order, "[i]n any communication with the FDA regarding IH, Avadel must inform the FDA that Avadel is enjoined from seeking approval for an IH indication for Lumryz until February 19, 2036, and Avadel must ensure it does not receive approval for IH during the term of this injunction." D.I. 746-1 ¶ 2.

II. LEGAL STANDARD

"Innumerable acts of Congress explicitly provide for injunctions,"[3] including the Patent Act, which provides that "[t]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity[4] to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283; *see TEK Glob., S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 792 (Fed. Cir. 2019) ("Our review is guided by statute and well-established principles of equity.").[5]

Under *eBay*, "[a] plaintiff seeking a permanent injunction must demonstrate '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'" *Oman Fasteners, LLC v. United States*, 125 F.4th 1068, 1083-84 (Fed. Cir. 2025) (quoting *eBay*, 547 U.S. at 391); *see Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328, 1341 (Fed. Cir. 2017).

"The movant must prove that it meets all four equitable factors." *Nichia Corp.*, 855 F.3d at 1341; *see Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156 (2010). "And it must do so on the merits of its particular case." *Nichia Corp.*, 855 F.3d at 1341; *see TD Bank N.A. v. Hill*,

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[3] *SEC v. Gentile*, 939 F.3d 549, 555-56 (3d Cir. 2019).

[4] "[T]reatises and handbooks on the 'principles of equity' generally contain transsubstantive guidance on broad and fundamental questions about matters like parties, modes of proof, defenses, and remedies." *Romag Fasteners, Inc v. Fossil, Inc.*, 590 U.S. 212, 217 (2020).

[5] "[T]he [Supreme] Court in *eBay* suggested that a 'major departure from the long tradition of equity practice' should be permitted *only* to the extent that 'Congress intended such a departure.'" *Ferring Pharms., Inc. v. Watson Pharms., Inc.*, 765 F.3d 205, 216 (3d Cir. 2014) (quoting *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391-92 (2006)).

928 F.3d 259, 265 (3d Cir. 2019) ("[C]ourts should issue injunctive relief only if the moving party makes a sufficient showing that such relief is warranted under the particular circumstances of that case.") (citing *eBay*, 547 U.S. at 393-94); *Salazar v. Buono*, 559 U.S. 700, 714 (2010) (plurality opinion) ("An injunction is an exercise of a court's equitable authority, to be ordered only after taking into account all of the circumstances that bear on the need for prospective relief.").

III. DISCUSSION

"[I]n equity, 'the broader and deeper the remedy the plaintiff wants, the stronger the plaintiff's story needs to be.'" *Trump v. CASA, Inc.*, 606 U.S. ___, 145 S. Ct. 2540, 2558 (2025) (quoting S. Bray & P. Miller, *Getting into Equity*, 97 Notre Dame L. Rev. 1763, 1797 (2022)). In this instance, Jazz seeks equitable relief that is unprecedented under both Federal Circuit law and Third Circuit law.[6] As explained below, Jazz has not established that its story warrants such relief.

A. Summary of Contentions[7]

1. Plaintiffs' Contentions[8]

Plaintiffs assert that "the Court should enjoin Avadel from requesting FDA approval for a Lumryz idiopathic hypersomnia indication." D.I. 747 at 3 (capitalization and emphasis altered).

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[6] To the extent that Federal Circuit and Third Circuit caselaw conflict, this Court "gives dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *FMC Corp. v. Sharda USA, LLC*, 145 F.4th 1326, 1330 (Fed. Cir. 2025) (quoting *Natera, Inc. v. NeoGenomics Lab'ys, Inc.*, 106 F.4th 1369, 1374 (Fed. Cir. 2024)); *see Hybritech Inc. v. Abbott Lab'ys*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1988). This Court "need not resolve which circuit's law should govern [if] [Federal Circuit] law and Third Circuit law are in relevant respects the same." *Uniloc USA, Inc. v. Motorola Mobility LLC*, 52 F.4th 1340, 1346 n.3 (Fed. Cir. 2022).

[7] Although the Court does not recite every proffered fact and contention, the Court has carefully and completely considered the parties' submissions. *Cf. Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1303 (Fed. Cir. 2009).

[8] Plaintiffs filed two declarations in support of their contentions: (1) the Declaration of Richard K. Bogan in Support of Plaintiffs' Renewed Motion for a Permanent Injunction (D.I. 748) and (2) the Declaration of Nathan Cortez (D.I. 749).

Plaintiffs contend that "[a]n injunction preventing Avadel from seeking FDA approval for IH is 'necessary to prevent future infringement' in the IH population." *Id.* (quoting *Jazz II*, 136 F.4th at 1089). Specifically, Plaintiffs contend that "an injunction preventing Avadel from requesting FDA approval for IH is necessary to prevent the harms this Court has recognized Jazz would suffer if Lumryz is marketed, made, used, or sold for IH prior to the expiration of the '782 patent." *Id.* at 3-4.

According to Plaintiffs, "[t]he record evidence demonstrates the following four facts: (1) unless Avadel is enjoined from requesting FDA approval to treat IH, once Avadel's trial is completed next year, Avadel will submit an application for IH; (2) Avadel expects the application will be swiftly approved;[9] (3) an IH indication will be included on Lumryz's label and Avadel will be marketing for IH, inducing physicians to prescribe and patients to use Lumryz for IH in violation of the injunction;[10] and (4) Avadel admits that FDA approval will result in the current injunction being violated." *Id.* at 5. Thus, Plaintiffs assert that "Avadel has no reason to request FDA approval ten years in advance of when it can sell Lumryz for IH" and "[a]llowing Avadel to

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[9] According to Plaintiffs, "Avadel expects to seek approval for IH in early 2026 after completion of its phase 3 clinical trial. . . . Once Avadel's clinical trial is completed, Avadel expects the FDA to take about ten months to review Avadel's application. By Avadel's timeline, the FDA would find Avadel approvable for IH by late 2026 or early 2027." *Id.* at 8-9 (citations omitted).

[10] According to Plaintiffs, "once Lumryz is approved to treat IH, the law requires that its labeling include that approved indication and be made public. At that point, Avadel will be marketing and selling Lumryz for IH, inducing physicians to prescribe and patients to use Lumryz for IH in violation of the injunction." *Id.* at 9. Moreover, according to Plaintiffs, "[o]nce IH is on the Lumryz label, Avadel will be marketing, making, using, and selling Lumryz for IH (despite the Court's injunction). In fact, Avadel will be inducing physicians to prescribe and patients to use Lumryz for IH." *Id.* at 11; *see id.* at 14 ("But the infringing *making* and *sale* by Avadel for uses other than treatment of narcolepsy is a violation of the current injunction regardless of whether Avadel is actively promoting Lumryz for IH. And, Avadel obtaining FDA approval before the '782 patent expires will induce direct infringement by physicians and patients in further violation of the injunction and the '782 patent.").

seek approval before February 19, 2036 would render the current injunction ineffective[.]" *Id.* at 15.

Plaintiffs also assert that "the *eBay* factors support this Court enjoining Avadel from requesting FDA approval for Lumryz to treat idiopathic hypersomnia." *Id.* at 15 (capitalization and emphasis altered).

As to the first *eBay* factor, Plaintiffs contend that "Avadel's request for approval of Lumryz to treat IH will cause Jazz irreparable harm." *Id.* at 15 (capitalization and emphasis altered); *see id.* at 16-18 ("Avadel's request for approval for Lumryz to treat IH will inevitably result in Jazz losing market share to Avadel, a direct competitor, which this Court has acknowledged constitutes irreparable harm. . . . Avadel's request for IH approval will inevitably result in Jazz suffering further price erosion, which this Court held constituted irreparable harm. . . . Avadel's request for IH approval inevitably will result in Jazz suffering irreparable reputational harm."); D.I. 768 at 9 ("Avadel seeking IH approval will inevitably result in Avadel selling more Lumryz for IH, irreparably harming Jazz.").

As to the second *eBay* factor, Plaintiffs contend that "monetary remedies will not adequately compensate Jazz." D.I. 747 at 19 (capitalization and emphasis altered); *see id.* ("[T]his factor [is] satisfied by evidence of Jazz suffering price erosion, loss of market share to a 'head-to-head competitor[],' and reputational harm from losing its exclusivity in the IH market. As explained above, each of these harms necessarily will result from Avadel's request for FDA approval for an IH indication for Lumryz.") (some alterations in original) (citation omitted).

As to the third *eBay* factor, Plaintiffs contend that "the balance of equities favors Jazz." *Id.* at 19 (capitalization and emphasis altered); *see id.* ("Avadel suffers no harm from enjoining an IH approval request until the '782 patent expires. . . . Avadel requesting approval for IH will

inevitably lead to Avadel marketing and selling Lumryz for IH, which will induce physicians and patients to infringe."); D.I. 768 at 10 ("Enjoining seeking FDA approval is necessary to stop expanded infringement and violation of the current injunction.").

As to the fourth *eBay* factor, Plaintiffs contend that "the injunction would not disserve the public interest." D.I. 747 at 20 (capitalization and emphasis altered); *see id.* ("[T]he only way to successfully ensure Lumryz is enjoined from the IH market is to prevent Avadel from requesting approval for an IH indication. Avadel is already enjoined from marketing, making, using, or selling Lumryz for IH.").

2. Defendant's Contentions[11]

Defendant responds that "Jazz's renewed motion seeking to enjoin Avadel from submitting a supplemental New Drug Application ('sNDA') for LURMYZ for the treatment of idiopathic hypersomnia ('IH') [] invites error." D.I. 757 at 1. Defendant asserts that "[p]roperly assessed, the *eBay* factors uniformly warrant rejecting Jazz's proposed injunction." *Id.*

As to the first and second *eBay* factors, Defendant contends that (1) "Jazz's assertions of future infringement are insufficient"; (2) "Jazz fails to account for Avadel's protective measures"; (3) "Jazz has not even attempted to show irreparable harm caused by approval for IH"; and (4) "Jazz's references to 'marketing' do not demonstrate irreparable harm from applying for approval to treat IH." *Id.* at 4 (capitalization and emphasis altered), 7 (same), 9 (same), 14 (same).

As to the third *eBay* factor, Defendant contends that "[u]nlike Jazz's speculative future harms, Jazz's overbroad injunction would harm Avadel in two immediate ways: (1) denying

[11] Defendant filed four declarations in support of its contentions: (1) the Declaration of Jennifer Gudeman (D.I. 758); (2) the Declaration of Gregory J. Divis (D.I. 759); (3) the Declaration of Meggan Sullivan (D.I. 760); and (4) the Declaration of Kira A. Davis (D.I. 761).

Avadel the opportunity to demonstrate Lumryz's clinical superiority to Xywav for IH; and (2) infringing on Avadel's constitutional rights." *Id.* at 16.

As to the fourth *eBay* factor, Defendant contends that "the public interest also favors allowing Avadel to seek approval for IH because LUMRYZ offers a potentially superior treatment." *Id.* at 20.

B. Analysis

1. Federal Circuit Precedent Forecloses Jazz's Attempt to Directly Enjoin Noninfringing Activities

Jazz seeks an injunction pursuant to Section 283. *See supra* Part I.C. "[A] trial court, upon a finding of infringement, must narrowly tailor an injunction to fit the specific adjudged violations." *Riles v. Shell Expl. & Prod. Co.*, 298 F.3d 1302, 1311 (Fed. Cir. 2002).[12] "Perhaps the most apparent restriction imposed by § 283 is that injunctions granted thereunder must 'prevent the violation of any right secured by patent.'" *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007). As explained below, the Federal Circuit's precedent governing the enjoinment of noninfringing activities forecloses the scope of the Section 283 injunction that Jazz seeks from this Court.

[12] "[D]istrict courts are frequently admonished . . . to restrict the scope of the injunction to the particular adjudicated infringing activity." *Jazz II*, 136 F.4th at 1082 (some alterations in original) (quoting *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1344 (Fed. Cir. 2012)). For example, the Federal Circuit has "held that 'the only acts [an] injunction may prohibit are infringement of the patent by the adjudicated [products] and infringement by [products] not more than colorably different from the adjudicated [products].'" *Forest Lab'ys, Inc. v. Ivax Pharms., Inc.*, 501 F.3d 1263, 1271 (Fed. Cir. 2007) (alterations in original) (quoting *Int'l Rectifier Corp. v. IXYS Corp.*, 383 F.3d 1312, 1316 (Fed. Cir. 2004)); *see id.* ("In order to comply with Rule 65(d), the injunction should explicitly proscribe only those specific acts.") (quoting 383 F.3d at 1316).

The Court first addresses the threshold issue of "whether Avadel . . . can be enjoined from seeking FDA approval for an idiopathic hypersomnia ('IH') indication for LUMRYZ™," which is an activity that the parties agree is noninfringing, under Section 283. D.I. 733 at 1.

In *Ortho Pharm. Corp. v. Smith*, the Federal Circuit remarked that "it is unclear whether [a] district judge has discretionary power under section 283 to issue [an] injunction covering acts not classified as infringement." 959 F.2d 936, 946 (Fed. Cir. 1992). The *Ortho Pharm.* panel was able to resolve the case before it without answering whether Section 283 injunctions can directly enjoin noninfringing activities. *See id.* ("Assuming, without deciding, he does have that power . . . ."). Based on the parties' "briefing and [the Court's] independent research,"[13] the Federal Circuit first answered that question a year later in *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993).[14]

In *Joy Techs.*, the Federal Circuit instructed that "[j]udicial restraint of lawful competitive activities[] [] must be avoided." 6 F.3d at 777.[15] According to a subsequent panel, which notably

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[13] *IOENGINE, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d 464, 516 (D. Del. June 15, 2022), *aff'd*, 136 F.4th 1354 (Fed. Cir. 2025). "Regardless of the parties' positions, '[w]hen an issue or claim is properly before the court, the court is not limited to the particular legal theories advanced by the parties, but rather retains the independent power to identify and apply the proper construction of governing law.'" *Spireon, Inc. v. Flex Ltd.*, 71 F.4th 1355, 1366 n.4 (Fed. Cir. 2023) (alteration in original) (quoting *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 99 (1991)).

[14] "Th[e] [Federal Circuit] has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *in banc*. Where there is direct conflict, the precedential decision is the first." *Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) (citation omitted); *see Biogen Int'l GmbH v. Banner Life Scis. LLC*, 424 F. Supp. 3d 303, 314 (D. Del. Jan. 7, 2020) ("In any event, even if there were a direct conflict between *Glaxo* and *Pfizer*, the Court would be bound to follow *Glaxo*, as it is the earlier of what would then be two conflicting precedential opinions of different panels of the Federal Circuit."), *aff'd*, 956 F.3d 1351 (Fed. Cir. 2020).

[15] Similarly, the Third Circuit has held that "[i]njunction orders should not restrain competitors from engaging in lawful business activities." *Mallet & Co. Inc. v. Lacayo*, 16 F.4th 364, 390 (3d Cir. 2021) (collecting cases).

issued its opinion after *eBay*, *Joy Techs.* "h[eld] that noninfringing acts may not be enjoined." *Paice*, 504 F.3d at 1314 (summarizing holding of 6 F.3d at 777).[16]

TiVo Inc. v. EchoStar Corp., 646 F.3d 869 (Fed. Cir. 2011) (en banc) adds a wrinkle, however. Although the Federal Circuit did not request briefing on the issue,[17] the majority in *TiVo* cited *Joy Techs.* for the proposition that the Federal Circuit "ha[s] never barred [judicial restraint of noninfringing activities] outright and instead ha[s] repeatedly stated that district courts are in the best position to fashion an injunction tailored to prevent or remedy infringement." 646 F.3d at 890 n.9 (dictum).[18]

Another wrinkle has formed from *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). The Federal Circuit in *Johns Hopkins* stated that "[i]n accordance with the clear wording of [] section [283], 'an injunction is only proper to the extent it is 'to prevent the violation

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[16] Notably, the *Paice* panel did not indicate that *Joy Techs.*' holding was "overruled by the . . . Supreme Court[']s [*eBay*] decision." *Texas Am. Oil Corp. v. U.S. Dep't of Energy*, 44 F.3d 1557, 1561 (Fed. Cir. 1995) (en banc).

[17] *See TiVo Inc. v. EchoStar Corp.*, 376 F. App'x 21, 21-22 (Fed. Cir. 2010) (granting petition for rehearing en banc).

[18] In the immediately subsequent sentence, the Federal Circuit stated "[b]ecause it is not before us in this case, we make no *en banc* holding on that issue." *Id.* Professor Golden has remarked that:

> The en banc majority's footnote suggests that the majority remained open to such relief but was at least somewhat suspicious of it. Moreover, five judges dissented from the portion of the majority opinion that contained this footnote. Their dissenting opinion used language that might be understood to indicate that the dissenters were significantly less open to the use of prophylactic injunctions[.]

John M. Golden, *Injunctions as More (or Less) Than "Off Switches": Patent-Infringement Injunctions' Scope*, 90 Tex. L. Rev. 1399, 1432 (2012). A "prophylactic injunction" is "prophylactic in the sense that [it] likely prohibit[s] some noninfringing activity or require[s] other activity that is beyond what is necessary to avoid infringement." *Id.* at 1428; *see* Restatement (Third) of Torts: Remedies § 44 cmt. e (A.L.I., Tentative Draft No. 2, Apr. 2023) ("*Prophylactic injunctions.* Some injunctions order defendant to refrain from conduct that is not unlawful in itself, or to act in ways that would not otherwise be legally required. Conduct that is enjoined although not necessarily illegal might have tortious consequences in the particular situation before the court, or defendant might be engaging in such conduct to achieve an unlawful purpose.").

of any right secured by patent.'"" 152 F.3d at 1365 (quoting *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 674 (Fed. Cir. 1990)). The Federal Circuit then cited *Joy Techs.* for the proposition that "judicial restraint of lawful noninfringing activities must be avoided." 152 F.3d at 1366 (quoting 6 F.3d at 777).[19] Nevertheless, the Federal Circuit recently interpreted *Johns Hopkins* as "explaining that an injunction may reach non-infringing activities, but that '[i]t is necessary ... that the injunction *prevent infringement*' of a patent." *Jazz II*, 136 F.4th at 1088 (alterations in original) (quoting 152 F.3d at 1367).[20]

Although "the Supreme Court has warned[that] categorical rules regarding permanent injunctions are disfavored,"[21] in light of the caselaw discussed above, a Section 283 injunction that directly enjoins noninfringing activities runs afoul of *Joy Techs.*' instruction that "[j]udicial restraint of lawful competitive activities[] [] *must be avoided.*" 6 F.3d at 777 (emphasis added). While the word "must" by itself can have multiple meanings,[22] in this context, the phrase "must

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[19] Understandably, some courts understood *Johns Hopkins* as leaving undisturbed *Joy Techs.*' instruction to avoid enjoining noninfringing activities. *See Metabolite Lab'ys, Inc. v. Lab'y Corp. of Am. Holdings*, 904 F. Supp. 2d 1137, 1142 (D. Colo. 2006) ("Enjoining 'noninfringing activities must be avoided.' . . . [A]n injunction issued pursuant to the Patent Act can enjoin only infringing conduct[.]") (quoting 152 F.3d at 1366). For example, one Federal Circuit panel stated that *Johns Hopkins* held that "the district court abused its discretion in ordering the repatriation of the exported vials under section 283, because the injunction was directed at activities that did not constitute infringement." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1343 (Fed. Cir. 2015) (summarizing holding of 152 F.3d at 1366).

[20] That same panel, however, also highlighted that "[d]istrict courts are frequently admonished . . . to restrict the scope of the injunction to the particular adjudicated infringing activity." *Jazz II*, 136 F.4th at 1082 (quoting *Aspex*, 672 F.3d at 1344).

[21] *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1343 (Fed. Cir. 2016) (citing *eBay*, 547 U.S. at 394). The Court is mindful that "[c]ircuit-court precedent is binding on district courts notwithstanding the mere possibility that the Supreme Court might come to disapprove that precedent." *In re Micron Tech., Inc.*, 875 F.3d 1091, 1098 (Fed. Cir. 2017).

[22] *See* Bryan A. Garner, *A Dictionary of Modern Legal Usage* 577 (2d ed. 1995) (entry for must).

be avoided" leaves no room for ambiguity. *See* Garner, *supra* note 22, at 94 (entry for avoid/void and avoidance/voidance). Thus, the *Paice* panel's interpretation that *Joy Techs.* "hold[s] that noninfringing acts may not be enjoined" is persuasive. *Paice*, 504 F.3d at 1314 (summarizing holding of 6 F.3d at 777).

"District courts are not free to ignore holdings of t[he] [Federal Circuit] that bear on cases before them."[23] *Joy Techs.* "is a binding precedential opinion issued by a panel of th[e] [Federal Circuit] and as such, 'cannot be overruled or avoided unless or until the [Federal Circuit] sits *en banc*.'"[24] Based on the parties' briefing and the Court's independent research, *Joy Techs.* has not been "overturned *in banc*." *Newell*, 864 F.2d at 765.[25] Thus, to the extent that "there [is] a direct conflict between [*Joy Techs.*] and [a subsequent panel], the Court would be bound to follow [*Joy Techs.*], as it is the earlier of what would then be two conflicting precedential opinions of different panels of the Federal Circuit." *Biogen*, 424 F. Supp. 3d at 314.

Even the *Jazz II* panel's more expansive view of Section 283 injunctions forecloses the scope of the injunction that Jazz seeks from this Court. For the reasons set forth in the portion of this Memorandum Order addressing the first two *eBay* factors, *see infra* Part III.B.2.a, this Court

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[23] *Texas Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996); *see* Bryan A. Garner et al., *The Law of Judicial Precedent* 155, 491 (2016).

[24] *Smith v. McDonough*, 112 F.4th 1357, 1364 (Fed. Cir. 2024) (quoting *Preminger v. Sec'y of Veterans Affs.*, 517 F.3d 1299, 1309 (Fed. Cir. 2008)).

[25] As explained earlier, *see supra* note 18, the *TiVo* majority expressly stated that it was not reaching the issue that is pertinent here. Thus, the *TiVo* majority's "statement was not a holding; it was expressly dictum and thus not binding." *TecSec, Inc. v. Int'l Bus. Machines Corp.*, 731 F.3d 1336, 1347 (Fed. Cir. 2013); *see R.R. Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1521-24 (Fed. Cir. 1984) (Nichols, J., concurring in the result) ("[J]udges over centuries have avoided dicta, or at least said they were doing so.").

"conclude[s] that [an] injunction [enjoining noninfringing acts] [is not] *necessary* to prevent infringement" under the particular circumstances of this case. *Jazz II*, 136 F.4th at 1088.

2. Jazz Has Not Made a Sufficient Showing under *eBay*

The Federal Circuit instructed that, if this Court "determines that th[e] [relevant] submission would not be an act of infringement," then this Court "must address the *eBay* factors anew in accordance with this opinion *before again enjoining that activity*." *Id.* at 1089 (emphasis added). While it is unclear whether a new *eBay* analysis is required since this Court declines to enjoin noninfringing activities, the Court will address the *eBay* factors anew "in the interest of thoroughness and to facilitate appellate review."[26]

"The four factors [that] [Jazz] must establish to secure a permanent injunction are: '(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.'" *V.O.S. Selections, Inc. v. Trump*, ___ F.4th ____, Nos. 2025-1812, 2025-1813, 2025 WL 2490634, at *17 (Fed. Cir. Aug. 29, 2025) (en banc) (quoting *eBay*, 547 U.S. at 391), *petition for cert. filed*, 2025 WL 2557077 (U.S. Sept. 4, 2025).

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[26] *Purpura v. Monroe Reg'l Med. Ctr.*, No. 5:13-CV-331-OC-22PRL, 2014 WL 12868861, at *3 n.8 (M.D. Fla. Sept. 16, 2014); *see AGCS Marine Ins. Co. v. World Fuel Servs., Inc.*, 187 F. Supp. 3d 428, 449 (S.D.N.Y. 2016) ("The foregoing holding is sufficient to support an award of summary judgment to World Fuel. However, in the interest of completeness and to facilitate anticipated appellate review, the Court also addresses World Fuel's two independent arguments for coverage."). The Court will not, however, unnecessarily address contentions that "are constitutional in scope." *Hindes v. F.D.I.C.*, 137 F.3d 148, 166 (3d Cir. 1998) ("Courts, of course, will avoid such questions where possible."); *see Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445 (1988) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them.").

As explained below, even assuming *arguendo* that courts can directly enjoin noninfringing activities under Section 283, *see Ortho Pharm.*, 959 F.2d at 946, the Court finds that Jazz has not "ma[de] a sufficient showing that such relief is warranted under the particular circumstances of th[is] case." *TD Bank*, 928 F.3d at 265 (citing *eBay*, 547 U.S. at 393-94).

a. Jazz Has Not Carried its Burden at *eBay* Factor 1 and Factor 2[27]

Under the first two *eBay* factors, Jazz "must establish . . . (1) that it has suffered an irreparable injury[, and] (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury[.]" *V.O.S. Selections*, 2025 WL 2490634, at *17. In this instance, as Jazz seeks to directly enjoin noninfringing activities, "entitlement to an injunction requires a showing that there is a 'causal nexus' between the alleged irreparable harm and the *enjoined activity*." *Jazz II*, 136 F.4th at 1089.[28] As explained below, Jazz has not carried its burden.

There are numerous ways that irreparable harm can be established. For example, "[h]ead-to-head competition and lost market share tend to evidence irreparable harm." *TEK Glob.*, 920

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[27] "Although *eBay* identified irreparable harm and the adequacy of legal remedies as separate considerations, they typically constitute two sides of the same inquiry, for the 'availability of adequate monetary damages belies a claim of irreparable injury.'" *TD Bank*, 928 F.3d at 282 (quoting *Bennington Foods LLC v. St. Croix Renaissance, Grp., LLP*, 528 F.3d 176, 179 (3d Cir. 2008)); *see* 7 Donald S. Chisum, *Chisum on Patents* § 20.04[2][c][iii] (Matthew Bender). Thus, "the Court will analyze the first two factors together[.]" *Premier Dealer Servs., Inc. v. Allegiance Adm'rs, LLC*, No. 2:18-CV-735, 2023 WL 2664411, at *4 (S.D. Ohio Mar. 28, 2023); *see Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1327 (Fed. Cir. 2008).

[28] "The causal nexus requirement ensures that an injunction is only entered against a defendant on account of a harm resulting from the defendant's wrongful conduct, not some other reason such as irreparable harm caused by otherwise lawful competition." *f'real Foods, LLC v. Hamilton Beach Brands, Inc.*, No. CV 16-41-CFC, 2020 WL 4015481, at *3 (D. Del. July 16, 2020) (quotation marks omitted) (quoting *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640 (Fed. Cir. 2015)); *see Macom Tech. Sols. Holdings, Inc. v. Infineon Techs. AG*, 881 F.3d 1323, 1330 (Fed. Cir. 2018).

at 793.[29] Moreover, "[a] patentee can be irreparably harmed by an alleged infringer's improper 'head start' and the loss of the 'first mover advantage' because the alleged infringer can capture market share and secure a competitive lead." *Incyte Corp. v. Sun Pharm. Indus., Ltd.*, 135 F.4th 1381, 1383-84 (Fed. Cir. 2025).

Importantly, "[s]peculative injury does not equate with irreparable harm, and the possibility that adequate compensatory and other relief will be available at a later date weighs against a finding of irreparable harm."[30] Thus, "an injunction cannot be fashioned when the prospect of future injury is only speculative; [] there must be a 'likelihood of substantial and immediate irreparable injury.'"[31] As explained below, the Court agrees with Defendant that "the required nexus [for irreparable harm] is absent []because the alleged future infringement is contingent on future events" that are remote and speculative. D.I. 757 at 4.

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[29] Similarly, "[t]he inherent difficulty of quantifying 'loss of market share, brand recognition, and customer goodwill' and of estimating monetary damages indicates that 'remedies at law are inadequate.'" *TEK Glob.*, 920 F.3d at 792 (quoting *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010)).

[30] *Flowserve Corp. v. Burns Int'l Servs. Corp.*, 423 F. Supp. 2d 433, 439 (D. Del. 2006) (citing *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 488 (3d Cir. 2000)); *see, e.g.*, *Todd v. Carstarphen*, 236 F. Supp. 3d 1311, 1325 (N.D. Ga. 2017) ("A permanent injunction . . . is issued only where the moving party establishes . . . an injury that is 'actual and imminent' . . . .") (quoting *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 896 F.2d 1283, 1285 (11th Cir. 1990)); *List v. Ohio Elections Comm'n*, 45 F. Supp. 3d 765, 780 (S.D. Ohio 2014) ("To demonstrate irreparable harm, the plaintiffs must show that ... they will suffer actual and imminent harm rather than harm that is speculative or unsubstantiated.") (alteration in original) (quoting *Abney v. Amgen, Inc.*, 443 F.3d 540, 552 (6th Cir. 2006)); *Aguilar v. Immigr. & Customs Enf't Div. of the U.S. Dep't of Homeland Sec.*, 811 F. Supp. 2d 803, 828 (S.D.N.Y. 2011) ("Irreparable harm is an injury that is not remote or speculative but actual and imminent, and for which a monetary award cannot be adequate compensation.") (quoting *Tom Doherty Assocs., Inc. v. Saban Ent., Inc.*, 60 F.3d 27, 37 (2d Cir. 1995)).

[31] *Gagliardi v. TJCV Land Tr.*, 889 F.3d 728, 734 (11th Cir. 2018) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983)).

First, as Defendant explains, Plaintiffs face a speculative injury that is not imminent if the Court declines to enjoin Defendant from seeking FDA approval for new indications of Lumryz:

> While Jazz asserts that enjoining Avadel from filing an sNDA is necessary to prevent future infringement, the Federal Circuit emphasized that the required nexus is absent where the alleged future infringement is contingent on future events. . . . "Although Avadel's ability to enter the market is, in part, dependent on Avadel seeking FDA approval, it does not follow that enjoining Avadel's sNDA would be *necessary* to prevent infringement" because "any number of things may prevent that approval from ever arriving." *Jazz*, 136 F.4th at 1089. Jazz presumes that the sNDA process will necessarily lead to IH sales. That is wrong and contrary to the Federal Circuit's decision for multiple reasons: (1) Avadel's clinical trial may not succeed; (2) applying for an IH indication for LUMRYZ does not necessarily mean that FDA will grant that application; . . . . neither Avadel's clinical study nor a possible sNDA filing will necessarily lead to infringement. Enjoining Avadel from filing an sNDA is simply not "necessary to prevent infringement," and Jazz fails to show the strong causal nexus for this reason alone. . . . *First*, while Avadel is currently running a clinical study on IH that is on track to complete enrollment by the end of 2025, neither that date nor the success of the clinical trial is assured. . . . *Second*, even if Avadel's clinical trial is successful and Avadel files its sNDA, there is no certainty as to when Avadel will make that filing. Gudeman Decl. at ¶ 10. Moreover, there is no certainty that FDA will approve that application. *Id.* at ¶ 11. These uncertainties belie Jazz's assertion that enjoining the filing of an sNDA is necessary to address infringement. *Third*, even if Avadel files an otherwise-approvable sNDA, Jazz's Xywav product still has ODE for IH, meaning that Avadel could only overcome that block by demonstrating that LUMRYZ is clinically superior to Xywav. . . . Given the foregoing, Jazz's claim of future infringement remains "speculative and tenuous," and its requested injunction is improper.

D.I. 757 at 4-7. The Court agrees that it would be a mistake to assume that "enjoining Avadel's application would be *necessary* to prevent infringement" merely because "Avadel's ability to enter the market is, in part, dependent on Avadel seeking FDA approval." *Jazz II*, 136 F.4th at 1089. Making that assumption would be "a classic non sequitur and [would] commit[] the fallacy of the consequent because the suggested conclusion does not follow logically from given premises or

any antecedent statements." *Magana v. Com. of the N. Mariana Islands*, 107 F.3d 1436, 1443 (9th Cir. 1997) (Aldisert, J.), *as amended* (May 1, 1997).

Taking into account all of the circumstances, the Court finds that "the possibility that adequate compensatory and other relief will be available at a later date weighs against a finding of irreparable harm." *Flowserve*, 423 F. Supp. at 439; *see BTL Indus., Inc. v. Advanced Regenerative Med. LLC*, No. CV 23-359-WCB, 2024 WL 455218, at *5 (D. Del. Feb. 6, 2024) ("Of course, if BTL is able to show irreparable harm from the defendants' patent infringement in the future, such as by showing that BTL has lost potential sales to customers who have purchased the defendants' infringing products, BTL can seek to amend the judgment to incorporate a provision extending the injunction to patent infringement.").[32]

Second, as Defendant explains, Plaintiffs face a speculative injury that is not imminent if Defendant obtains FDA approval for new indications of Lumryz.

As Defendant explains, it has already taken, and continues to take, numerous steps that minimize the likelihood of future infringement:

> Avadel has proactively implemented various measures to stop sales for IH. LUMRYZ is distributed only through specialty pharmacies with whom Avadel works closely. Sullivan Decl. at ¶ 4. Prescriptions can be filled only for registered patients. *Id.* When a physician prescribes LUMRYZ, they must identify the indication for which it is being prescribed. *Id.* That prescription is then submitted to a specialty pharmacy. *Id.* The specialty pharmacies then have license to either fill or refuse the prescription. *Id.* Avadel has written letters to the pharmacies explaining the Court's injunction so that they know to decline to fill prescriptions for IH. *Id.* at ¶ 7, Exs. 1-3. Avadel has also worked with Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs) so that they too know about the injunction and can help stop sales of LUMRYZ for IH. Divis Decl.

[32] Moreover, Plaintiffs' contention that "Avadel requesting approval for IH will inevitably lead to Avadel marketing and selling Lumryz for IH, which will *induce* physicians and patients to infringe," D.I. 747 at 19 (emphasis added), overlooks that "the proofs required for determining future infringing activity are not insignificant and not amenable to a narrowly tailored order[.]" *Fuji Photo Film Co. v. Jazz Photo Corp.*, 394 F.3d 1368, 1380 (Fed. Cir. 2005) ("[T]he district court did not abuse its discretion in denying Fuji's request for a permanent injunction.").

> at ¶ 3; Davis Decl. at ¶ 4, Ex. C. In addition to sending letters to prevent IH sales of LUMRYZ, Avadel developed a call script for staff who are trained to respond to prescriber questions with a reminder that Avadel is not permitted to sell LUMRYZ for anything other than the treatment of narcolepsy. Sullivan Decl. at ¶ 8, Ex. 4. While there have been a small number of sales for non-narcolepsy indications (including to patients prescribed LUMRYZ off-label before the injunction, which sales are allowed to continue), Avadel has repeatedly communicated its injunction to its specialty pharmacies and will keep investigating any possible non-narcolepsy prescriptions. Sullivan Decl. at ¶¶ 6, 9. . . . Indeed, Avadel has scrupulously complied with the Court's order, including by informing all specialty pharmacies, PBMs, and GPOs, to prevent infringing sales. . . . Avadel will not actually make such sales unless the Court permits it—as it has repeatedly said in its marketing materials and public statements. Divis Decl. at ¶ 2. Given these effective steps that Avadel continues to take to prevent the making, using, and selling of LUMRYZ for IH, there is no strong causal nexus between Avadel's filing for approval and actual infringement. . . . The relevant evidence shows that Avadel does not market LUMRYZ for any non-narcolepsy indication and will continue to refrain from doing so as long as the Court's injunction remains in effect. Thus, no irreparable harm will come to Jazz. . . . Second, even if LUMRYZ is approved for IH and the revised label is disseminated by Avadel as Jazz argues, that would not overcome the other protective measures Avadel has taken to prevent marketing for IH.

D.I. 757 at 8-9, 12-15.

Moreover, as Defendant explains, if it obtains FDA approval, then it can and will take numerous, additional steps that minimize the likelihood of future infringement:

> If Avadel were to obtain FDA approval, Avadel would send new letters to the pharmacies, GPOs, and PBMs. Divis Decl. at ¶ 4. Although IH would no longer be "off-label," its use for IH would still be enjoined, setting aside for the moment the merits appeal and any motion by Avadel to lift the injunction. Avadel would therefore once again inform the relevant parties of the injunction so as to stop LUMRYZ prescriptions for any non-narcolepsy indication, including IH. *Id.* . . . Avadel will not actually make such sales unless the Court permits it—as it has repeatedly said in its marketing materials and public statements. Divis Decl. at ¶ 2. Given these effective steps that Avadel continues to take to prevent the making, using, and selling of LUMRYZ for IH, there is no strong causal nexus between Avadel's filing for approval and actual infringement. . . . The relevant evidence shows that Avadel does not market LUMRYZ for any non-narcolepsy indication and will continue to refrain from doing so as long as the Court's injunction remains in effect. Thus, no irreparable harm will come to Jazz. . . . When considering Avadel's past statements that LUMRYZ is enjoined from non-narcolepsy indications and commitment to maintain those statements while the injunction is in effect, approval of LUMRYZ for IH will not necessarily lead to marketing of LUMRYZ for the treatment of IH.

D.I. 757 at 9 n.1, 12-16.

In this instance, Defendant's representations about the steps it has taken in the past, and the steps it will take in the future, to avoid violating the existing injunction "tempers [P]laintiffs' need for injunctive relief" enjoining noninfringing activities. *Ameritox, Ltd. v. Millennium Health, LLC*, No. 13-CV-832-WMC, 2015 WL 3825499, at *3 (W.D. Wis. June 19, 2015) ("Here, Millennium *does* represent that it will stop using the infringing materials and, with an isolated exception, has made good on its representation. Because of this, the court is content that the new RADAR Report demonstrates Millennium's *bona fides* to cease infringement of the '680 patent, despite the inadvertent use on April 20–22, 2015. This tempers plaintiffs' need for injunctive relief."); *see Accentra Inc. v. Staples, Inc.*, 851 F. Supp. 2d 1205, 1240 (C.D. Cal. 2011) ("Finally, the Court rejects Accentra's position that an injunction should issue because the injunction will have little negative impact on Staples if Staples is telling the truth about its intent not to infringe in the future. This approach is logically flawed because the opposite could be equally true: if Staples is telling the truth about not intending to infringe in the future, then an injunction is unnecessary."), *aff'd in part on other grounds, rev'd in part on other grounds and remanded*, 500 F. App'x 922 (Fed. Cir. 2013).

Thus, in this instance, Plaintiffs "inability to show irreparable harm—or, relatedly, that a legal remedy would be inadequate—defeats [their] request for injunctive relief" enjoining Defendant from seeking FDA approval for new indications of Lumryz. *TD Bank*, 928 F.3d at 278; *see Verinata Health, Inc. v. Ariosa Diagnostics, Inc*, 809 F. App'x 965, 976-77 (Fed. Cir. 2020) (nonprecedential) ("Because Illumina failed to establish irreparable injury and inadequacy of monetary relief, the district court did not abuse its discretion in denying Illumina's request for a permanent injunction."). "Given [the Court's] conclusions regarding irreparable harm and the

remedies available at law, [the Court] need not make any findings concerning the balance of hardships and public interest factors." *MHL Custom, Inc. v. Waydoo USA, Inc.*, No. CV 21-0091-RGA, 2023 WL 5805889, at *5 (D. Del. Sept. 7, 2023). Nevertheless, the Court will address the remaining *eBay* factors "in the interest of thoroughness and to facilitate appellate review." *Purpura*, 2014 WL 12868861, at *3 n.8.

b. Jazz Has Not Carried its Burden at *eBay* Factor 3

Under the third *eBay* factor, Jazz "must establish . . . (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted[.]" *V.O.S. Selections*, 2025 WL 2490634, at *17.

In this instance, even without considering the merits of Defendant's contentions that are constitutional in scope,[33] the Court finds that Jazz has not "show[n] that the balance of hardships weighs in its favor." *Wonderland Switzerland AG v. Evenflo Co., Inc.*, No. 1:20-CV-00727-JPM, 2023 WL 4098571, at *7 (D. Del. June 7, 2023) (quoting *Samsung*, 809 F.3d at 645). As explained earlier, *see supra* Part III.B.2.a, "there is no evidence that an injunction [enjoining noninfringing activities] is necessary to avoid hardship to [Plaintiffs]." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1341 (Fed. Cir. 2012).

On the other hand, as Defendant explains, an injunction directly enjoining noninfringing activities would cause Defendant hardship, because it would constrain and delay potential paths to lawfully commercializing the use of Lumryz for IH:

> Jazz argues that it will suffer harm from competing sales and that Avadel will suffer no harm whatsoever. Jazz is wrong. Jazz will not suffer any lost sales, price erosion, or reputational harm from a LUMRYZ sNDA requesting FDA approval for the treatment of IH. Nor will it suffer any of those harms if LUMRYZ is approved for that indication. Avadel is able to—and commits to—take steps to stop sales of

[33] As explained earlier, the Court restrains from unnecessarily addressing such contentions. *See supra* note 26.

> LUMRYZ for the treatment of IH until and unless the injunction on the making, using, or selling of LUMRYZ for the treatment of IH is lifted. *Supra* at § III.A.2. On the other, Jazz's attempt to foreclose FDA's consideration of ODE for IH and deny Avadel its right to petition the government causes real harm to Avadel. FDA already determined that LUMRYZ is clinically superior to Xyrem and Xywav for narcolepsy based on once-nightly dosing. Avadel expects that it will determine the same for IH for the same reason. Indeed, FDA has already awarded LUMRYZ ODD for IH on this basis. *See* § III.D, *infra*. FDA should be able to determine whether to award ODE, and if so, Avadel should have the ability to present that fact to the Court.

D.I. 757 at 19-20.

Thus, Plaintiffs inability to show that the balance of hardships weighs in their favor defeats their request for injunctive relief enjoining Defendant from seeking FDA approval for new indications of Lumryz. *See Oman Fasteners*, 125 F.4th at 1083-84 ("A plaintiff seeking a permanent injunction must demonstrate '. . . (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted[.']") (quoting *eBay*, 547 U.S. at 391).

c. Jazz Has Not Carried its Burden at *eBay* Factor 4

Under the fourth *eBay* factor, Jazz "must establish . . . (4) that the public interest would not be disserved by a permanent injunction." *V.O.S. Selections*, 2025 WL 2490634, at *17.

Generally, "[t]o determine where the public interest lies, a court should weigh the 'advantages and disadvantages' to the public of 'employing the extraordinary remedy of injunction over the other available methods of enforcement.'" *TD Bank*, 928 F.3d at 284 (quoting *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 498 (2001)).

"Although enforcing the right to exclude serves the public interest, the public interest factor requires consideration of other aspects of the public interest." *ActiveVideo*, 694 F.3d at 1341. With respect to injunctions issued under Section 283, "[t]he 'touchstone of the public interest factor is whether an injunction, both in scope and effect, strikes a workable balance between

protecting the patentee's rights and protecting the public from the injunction's adverse effects.'" *TEK Glob.*, 920 F.3d at 793 (Fed. Cir. 2019) (quoting *i4i*, 598 F.3d at 863).[34]

Defendant contends that an injunction enjoining noninfringing activities would disserve the public "because LUMRYZ offers a potentially superior treatment" (D.I. 757 at 20):

> The public interest also favors allowing Avadel to seek approval for IH because LUMRYZ offers a potentially superior treatment. As the Court recognized, the "FDA's superiority determination strongly indicates that the public interest favors the availability of LUMRYZ for narcolepsy." D.I. 665 at 19. On June 4, 2025, FDA granted LUMRYZ ODD for IH "based on the plausible hypothesis that [LUMRYZ] may be clinically superior to the same drug(s) already approved for the same indication because [LUMRYZ] may provide a major contribution to patient care due to [LUMRYZ]'s once nightly dosing for patients with IH, a chronic sleep disorder that requires potentially lifelong treatment." Ex. 2 at 1 (FDA, June 4, 2025 Orphan Drug Designation). Jazz makes two arguments. First, Jazz argues that the Court "already found 'the public interest weighs in favor of enjoining LUMRYZ in the IH market.'" D.I. 747 at 20 (citing D.I. 665 at 25-29). Second, Jazz cites to the Court's prior finding that "Avadel has not [and cannot] show[] that LUMRYZ offers any other distinct benefits to patients with IH." *Id.* 20 (citing D.I. 665 at 28). But FDA's grant of ODD for IH fundamentally changes the landscape and should alter those findings. Jazz's failure to address ODD suggests that it has no answer.

D.I. 757 at 20 (alterations in original). In this instance, for the reasons set forth above (*see supra* Part III.B.2.a), the Court finds that an injunction can "strike[] a workable balance between protecting [] [Plaintiffs'] rights and protecting the public from the injunction's adverse effects" without enjoining Defendant from seeking FDA approval for new indications of Lumryz. *i4i*, 598 F.3d at 863.

Importantly, under the particular circumstances of this case, an injunction can strike such a balance without "Jazz [] receiv[ing] a *de facto* extension of patent term to which it is not otherwise entitled for the amount of time it takes the FDA to consider and grant [Defendant's]

[34] The Court is also mindful that "eliminating a choice of drugs is not, by itself, sufficient to disserve the public interest." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017).

application," *Jazz II*, 136 F.4th at 1088,[35] and without permitting infringement. *Cf. Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008) ("We agree that the sunset provisions mitigate the harm to the public and that the district court did not abuse its discretion in fashioning a remedy that protects Broadcom's rights while allowing Qualcomm time to develop non-infringing substitutes.").

"Thus, on balance, the public interest here also militates against [a] permanent injunction" that would enjoin Defendant from seeking FDA approval for new indications of Lumryz. *TD Bank*, 928 F.3d at 285-86; *see Amgen*, 872 F.3d at 1381 ("If a plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction.") (quoting *eBay*, 547 U.S. at 391).

IV. CONCLUSION

For the foregoing reasons, the Court finds that Jazz seeks "prospective relief that [does not] fit[] the remedy to the wrong or injury that has been established," *Salazar*, 559 U.S. at 718, and the Court denies Plaintiffs' Renewed Motion for a Permanent Injunction (D.I. 746).[36]

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[35] As a general rule, a windfall *de facto* extension of a patent's term that Congress has not provided for disserves the public interest. *See, e.g.*, *United States v. Univis Lens Co.*, 316 U.S. 241, 251-52 (1942) ("In construing and applying the patent law so as to give effect to the public policy which limits the granted monopoly strictly to the terms of the statutory grant, the particular form or method by which the monopoly is sought to be extended is immaterial.") (citation omitted); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (noting that one "purpose[] of the federal patent system . . . [is] to permit the public to practice the invention once the patent expires"); *Eldred v. Ashcroft*, 537 U.S. 186, 223 (2003) (Stevens, J., dissenting) ("[T]he requirement that those exclusive grants be for 'limited Times' serves the ultimate purpose of promoting the 'Progress of Science and useful Arts' by guaranteeing that those innovations will enter the public domain as soon as the period of exclusivity expires[.]").

[36] Within fourteen (14) days of entry of this Memorandum Order, the parties shall meet and confer to discuss whether the preexisting injunction order complies with Rule 65(d), which "requir[es] clear notice as to what [an enjoined] party must do or refrain from doing." *Abbott v. Perez*, 585 U.S. 579, 598 (2018); *see, e.g.*, *TiVo*, 646 F.3d at 884-88; *Macom*, 881 F.3d at 1331-32; *Inguran, LLC v. ABS Glob., Inc.*, 72 F.4th 1272, 1280-81 (Fed. Cir. 2023). To the extent that either side

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WHEREFORE, at Wilmington this 8th day of September 2025, **IT IS HEREBY ORDERED** that Plaintiffs' Renewed Motion for a Permanent Injunction (D.I. 746) is **DENIED**. Because this Memorandum Order is filed under seal, the parties shall meet and confer and, no later than fourteen (14) days after entry of this Memorandum Order, file a proposed redacted version of the Memorandum Order, along with a motion supported by a declaration that contains a clear, factually detailed explanation as to why disclosure of any proposed redacted material would "work a clearly defined and serious injury to the party seeking closure." *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). If the parties do not file a proposed redacted version and corresponding motion by the deadline, or if the Court determines the motion lacks a meritorious basis, this Memorandum Order will be unsealed in whole or in part.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

contends that the preexisting injunction order does not comply with Rule 65(d), and the parties are unable to agree on a stipulated proposed injunction order, then within thirty (30) days of entry of this Memorandum Order, the parties shall submit a joint letter, not to exceed three (3) pages, that (1) identifies the specific issues that remain in dispute; (2) sets forth each side's position on each dispute and the legal authority for each side's respective position; and (3) explains why the parties were unable to reach agreement on each issue.